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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,156	12/11/2003	Juan A. Vergez	PHUS-104	5954

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EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
09/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,156	VERGEZ ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-12,32,41-44 and 48-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12,32 and 41-44* is/are rejected.

7)☒ Claim(s) *48-52* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed on 05/22/2208. Upon entering the amendment, the claims 2-3, 21-31 and 45-57 are cancelled and claims 1, 4, 6, 8, 10, 12, 32, 41-44 and 48 have been amended. Accordingly, claims 1, 4-12, 32, 41-44 and 48-52 are pending and presented for the examination.

Response to Arguments

2. Applicant's arguments filed on 05/22/2008 with respect to claims have been fully considered but they are not persuasive. The 103(a) rejection of Wong et al (US 4,783,337) and Faour (US 6,352721) in view Savastano et al (US 5,681,584) and Smolka et al (WO 2003/097041 A1) is maintained and made **FINAL**.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 4-12, 32 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Wong et al (US 4,783,337 here after '387) and Faour (US 6,352,721 here after '721) in view Savastano et al (US 5,681,584 here after '584) and Smolka et al (WO 2003/097041 A1 here after '041).

The '337 patent discloses an osmotic device possessing dual osmotic activity that operates as an integrated unit, comprising a compartment containing a first osmotic composition comprising a drug, and preferably an osmopolymer and/or an osmagent, and a second and different osmotic composition with the compositions acting in concert for delivering the drug through a passageway of controlled dimensions from the osmotic device (see column 3, lines 22-31). The '337 patent also discloses the use of osmotic therapeutic device that possesses the ability to delivery drugs over a broad range of drug delivery rates, and can deliver the drugs according to a predetermined drug release rate pattern to a biological recipient over a desired time period (see column 4, lines 10-15). The '337 patent also discloses the active agents used herein includes any beneficial agent or compound that can be delivered from the device to produce a beneficial and useful results in animals, including warm blooded mammals, humans and primates thereof (see column 19, lines 33+).

The '721 patent discloses an osmotic device capable of delivering active substances comprising an centrally located core comprising a hydr0philic expandable polymer and, optionally, an osmagent, wherein the core is surrounded by a composition comprising at least one active agent and preferably an osmagent and/or osmopolymer, a membrane immediately surrounding the composition, and at least one preformed

passageway and plural micropores in the membrane that communicate the composition with the outside of the device. The '721 patent also discloses a osmotic therapeutic device for the delivery of pharmaceutically active agents, ranging in solubility from slightly soluble to very soluble drugs, in a controlled, continuous and approximately steady, preferably zero order, rate over a prolonged period of time (see column 3, lines 18-33+). The '721 patent further discloses the use of active agents such as biologically or pharmaceutically active agents, medicines, nutrients and other agents that benefit the environment of use (see column 4, lines 4-30).

The combination of '337 and '721 teaches most essential elements of the invention. However '337 and '721 patents fails to teach specifically the use of licofelone as one of the pharmacologically active substance that produces a local or systemic effect in humans and primates. The prior art provides tools of powerful osmotic devices for delivering a beneficial agent at controlled and continuous rate over a prolonged period of time to an environment of use. The use of osmotic device comprising a wall surrounding a compartment and has a passageway through the wall for delivering active agents is well documented.

The '584 patent discloses a drug delivery device for delivering a drug either intermittently, or to a pre-selected region of the gastro-intestinal tract (colon) consists of an solid core comprising an active agent coated with a delay jacket, then coated with a semi-permeable membrane which is optionally drilled to provide a release orifice, and then optionally further coated with an enteric material (see abstract). And active agent includes proteins and peptides, antiasthamtics, antianginals, anti-inflammatory agents,

5-1ipoxygenase inhibitors and virtually any other active agent which is known to be colonically absorbable or used to topically treat the colon can be used as an active agent (see col. 6, lines 33-65). And also core include an osmotic agent to affect the desired release profile, suitable osmotic agents include pharmaceutically acceptable salts of inorganic and organic acids such as sodium or potassium or magnesium chloride, and the like (see col. 7, lines 10-45). And further core excipients include tabletting lubricants, glidants, and wetting agents to aid in dissolution of the components, binders and suspending agents. Binder such as hydroxypropyl methylcellulose, polyethylene oxide, polyvinylpyrrolidone and mixtures thereof (see col. 8, lines 1-20).

Smolka et al., discloses a method for treating and preventing gastric acid related conditions (effectively treating inflammatory conditions while having gastric sparing properties or preventing the pathologic changes involved therewith) in mammals with ML3000 (licofelone) dosage forms (see page 10, lines 35 and page 11, lines 1-3). And also the pharmaceutical preparations can be in a solid form e.g. tablets, capsules, and the like, in which an erodible matrix (bio-erodible polymers e.g. various cellulosic polymers and natural materials) or series of coating is used to provide a continuous release or extended release of the drug. And further discloses the pharmacokinetic properties of the pharmaceutical preparation (ML3000) and in particular to the time from administration of the drug until Cmax is obtained and until plasma levels of the active component is decreased below a certain level (see page 16, lines 21-31 and page 17, lines 20-28).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate licofelone active agent to provide an improved osmotic device for delivering the drugs as taught by '337 and '721patents. In view of Savastano and Christgau, motivation would come from a device for delivering substantially all of the active agent to the target site. Therefore, given the general teachings of the combined references, as to use of an osmotic device that can deliver various therapeutically active agents and has an economic advantage for the user by keeping to a minimum the number of doses to be administrated and reducing missed doses because of forgetfulness, one of ordinary skill in the art at the time of the invention was made would have reasonable expectation of success to modify the biologically or pharmaceutically active agents of '337 and '721 thereby, making the drug available instantly to a drug receptor by substantially eliminating the start-up drug delivery time frequently required to deliver some drugs by osmotic device for performing its beneficial effects.

Applicant's arguments filed on 05/22/2008 have been fully considered but they are not persuasive.

Applicant assert that examiner fails to rely upon (WO 2005/123130) PCT Publication and improperly relies upon (WO 2003/097041).

Examiner respectfully submit that here is a topographical error in citing the (WO 2005/123130) PCT Publication. The PCT Publication should read as Smolka et al (WO 2003/097041 A1) as used in the 103(a) rejection.

Applicant's assets that examiner rejection is based upon hindsight reconstruction to arrive at the invention claimed.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant also assets that the prophetic combination of art fails to provide motivation to prepare an osmotic device as defined in the instant claims.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed.Cir. 1986).

In this case, the Wong et al. and Faour patent is relied upon to show that it is known in the art to construct a osmotic device that can be used for delivering numerous agents including drugs at a controlled rate independent of the drug pH dependency, or where the dissolution rate of the agent can vary between low and high in fluid environments, such as gastric fluid and intestinal fluid. The osmotic devices also provide for low/high loading of agents of low solubility and their delivery at meaningful, therapeutic amounts. And further, Faour patent discloses that the therapeutic device is capable of delivery of pharmaceutically active agents, ranging in solubility from slightly

soluble to very soluble drugs, in controlled, continuous and approximately steady, Preferably zero order, rate over a prolonged period of time. Applicant also argue that smolka et al reference fail to provide specified release profile of the drug. Applicant's arguments are not persuasive because the motivation to combine the teachings of Smolka with that of Wong and Faour comes from the teaching of Smolka to show that pharmaceutical composition can be used for prevention and treatment of gastric-acid related conditions, especially gastrointestinal, disorders and also contemplates co-administration of the drugs to be given in combinations in accordance with different but regular and continuous dosing schedules whereby desired plasma levels of the drugs involved were maintained in the mammal being treated. The properties of the same drug (licofelone) would inherently have the same release profile when incorporated into the osmotic device and can deliver the drug (licofelone) according to a predetermined drug release rate pattern to a biological recipient over a prolonged period of time.

Allowable Subject Matter

4. Claims 48-52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

1. No claims are allowed at this time.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr